EXHIBIT A

STATE OF NEW YORK :
SUPREME COURT : COUNTY OF ERIE

TRACEY HALLAC
5727 Strickler Road
Clarence, New York 14031

Plaintiff

vs

SUMMONS
Served with Complaint
Index #

ETHICON, INC.
Route 22 West
Somerville, New Jersey 08876

JOHNSON & JOHNSON
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933

Defendants

To the above named Defendants:

YOU ARE HEREBY SUMMONED AND REQUIRED to serve upon the Plaintiff's attorneys, at the address stated below, a written Answer to the attached Complaint.

If this Summons is served upon you within the State of New York by personal service you must respond within **TWENTY (20)** days after service, not counting the day of service. If this Summons is not personally delivered to you within the State of New York you must respond within **THIRTY (30)** days after service is completed, as provided by law.

If you do not respond to the attached Complaint within the applicable time limitation stated above, a Judgment will be entered against you, by default, for the relief demanded in the Complaint, without further notice to you.

This action is brought in the County of Erie because of:

[X] Plaintiff's residence, or place of business;
[ ] Defendant's residence;
[ ] Designation made by Plaintiff.

DATED: Buffalo, New York
March 17, 2023

Theresa M. Walsh, Esq.
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STATE OF NEW YORK :
SUPREME COURT : COUNTY OF ERIE

TRACEY HALLAC

Plaintiff

vs.

COMPLAINT
Index #_____

ETHICON, INC.;
JOHNSON & JOHNSON,

Defendants

PLAINTIFF, TRACEY HALLAC, by her attorneys, BROWN CHIARI LLP, for her Complaint in the above-entitled action alleges:

1. Plaintiff, TRACEY HALLAC, at all times herein mentioned, has been a resident of the State of New York.

2. Upon information and belief, Defendant ETHICON, INC. is a foreign corporation authorized to do business in the State of New York with an office for business located at least at Route 22 West, Somerville, New Jersey 08876.

3. At all relevant times herein mentioned, Defendant ETHICON, INC. conducted regular and sustained business in New York by selling and distributing its products in New York.

4. Upon information and belief, Defendant JOHNSON & JOHNSON is a foreign corporation authorized to do business in the State of New York with an office for business located at least at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

5. At all relevant times herein mentioned, Defendant JOHNSON & JOHNSON conducted regular and sustained business in New York by selling and distributing its products in New York.

6. Upon information and belief, Defendant ETHICON, INC. is a wholly owned subsidiary of Defendant JOHNSON & JOHNSON.

7. Upon information and belief Defendant JOHNSON & JOHNSON is, or at all times relevant was, a parent corporation of Defendant ETHICON, INC. and as such assumes liability for the said defendant with respect to this matter. Upon information and belief, Defendant JOHNSON & JOHNSON operated, controlled, managed, directed, administered, and/or assumed responsibility for Defendant ETHICON, INC.

8. Defendants, at all times herein mentioned, engaged in the developing, inspecting, testing, assembling, designing, licensing, labeling, manufacturing, distributing, packaging, supplying, marketing, advertising and/or selling, either directly or indirectly through third parties or related entities, the Physiomesh Flexible Composite device.

9. The Defendants knew, or should have known, that the Physiomesh Flexible Composite device was defective and not safe and/or effective as originally developed, inspected, tested, assembled, designed, licensed, labeled, manufactured, distributed, packaged, supplied, marketed, advertised and/or sold.

10. The Defendants' Physiomesh Flexible Composite device was defectively designed and/or manufactured, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design.

11. As a result of the defective design and/or manufacture of the Physiomesh Flexible Composite device, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic pain, recurrence of hernia, foreign body response, rejection, infection, inadequate or failure of incorporation/ingrowth, migration, scarification, deformation of

mesh, improper wound healing, excessive and chronic inflammation, adhesions to internal organs, erosion, abscess, fistula formation, granulomatous response, seroma formation, nerve damage, tissue damage, death, and/or other complications.

12. The Physiomesh Flexible Composite device had a unique design incorporating five (5) distinct layers: two layers of poliglecaprone-25 ("Monocryl") film covering two underlying layers of polydioxanone film ("PDS"), which in turn coat a polypropylene mesh. This design is not used in any other hernia repair product sold in the United States. The multi-layer coating was represented and promoted by the Defendants to prevent or minimize adhesion and inflammation and to facilitate incorporation of the mesh into the body, but it did not. Instead, the multi-layer coating prevented adequate incorporation of the mesh into the body and caused or contributed to an intense inflammatory and chronic foreign body response resulting in an adverse tissue reaction including migration and damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper healing.

13. When implanted intraperitoneally, which involves the abdomen being inflated and then deflated, and the product being implanted in contact with the intestines and/or other internal organs, the Physiomesh Flexible Composite device design unnecessarily increased the risks of mesh deformation, adhesion, erosion, fistula formation, and other injuries. When implanted using an open procedure, the Physiomesh Flexible Composite device design provided no benefit, and instead increased the risks associated with the product.

14. When affixed to the body's tissue, the impermeable multi-layer coating of the Physiomesh Flexible Composite device prevented fluid escape, which lead to seroma formation, and which in turn can cause infection, abscess formation and other complications.

15. The multi-layer coating provided a breeding ground for bacteria in which the bacteria cannot be eliminated by the body's immune response, which allowed infection to proliferate.

16. The multi-layer coating of Defendants' Physiomesh Flexible Composite device was not biocompatible, which caused or contributed to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

17. The Defendants knew or should have known of the lack of biomcompatibility of the multi-layer coating of the Physiomesh Flexible Composite device prior to introducing it into the stream of commerce.

18. The polypropylene material used in the Physiomesh Flexible Composite device was unreasonably susceptible to in vivo oxidative degradation, which causes or exacerbates excessive inflammation and adverse foreign body reaction, leading to shrinkage, scarification, pain and mesh deformation.

19. The polypropylene mesh portion of the Physiomesh Flexible Composite device lacked sufficient strength to withstand normal abdominal forces, which resulted in recurrent hernia formation and/or rupture and deformation of the mesh itself.

20. When the multi-layer coating of the Physiomesh Flexible Composite device is disrupted and/or degrades, the "naked" polypropylene mesh is exposed to the adjoining tissue and viscera, and can become adhered to organs, and cause damage to organs, and potentiate fistula formation.

21. The Physiomesh Flexible Composite device e was often sold and/or implanted with a "SecureStrap" fixation device, also designed, manufactured, distributed and sold by Defendants, which exacerbated the risks, as well as the frequency, severity and duration of the risks, associated with the design of the Physiomesh product.

22. The Defendants also negligently failed to warn or instruct the Plaintiff or her physicians regarding the risks and defects associated with the Physiomesh Flexible Composite device, including those described herein above, which include but are not limited to: failing to adequately warn the Plaintiff or her physicians that the multi-layer coating of the Physiomesh Flexible Composite device preventing adequate incorporation of the mesh resulting in an intense inflammatory and chronic foreign body response, adverse tissue reaction, migration, and damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue and improper healing.

23. The Defendants provided no warning to the Plaintiff or their physicians about the risks or increased risks specifically associated with the unique design of the Physiomesh Flexible Composite device. The Defendants' Instructions for Use provided with the Physiomesh Flexible Composite device expressly understates and misstates the risks known to be associated specifically with the Physiomesh by stating that "Potential adverse reactions are those typically associated with surgically implantable materials." No other surgical mesh sold in the United States – and no other "surgically implantable material" – has the same design as Physiomesh Flexible Composite device. No other device or material contains the dangerous and defective multi-layer coating, which itself causes or increases the risks of numerous complications, including prevention of incorporation, increased risk of seroma formation, immunologic response, increased risk for infection, and increased inflammatory reaction and foreign body response. Defendants provided no warning to Plaintiff or her physicians about the risks or increased risks specifically associated with use of the SecurStrap with the Physiomesh Flexible Composite device product, which was intended and sold by Defendants specifically for use in the implantation of Physiomesh.

24. The Defendants' Instructions for Use for the Physiomesh Flexible Composite device also failed to adequately warn Plaintiff or her physicians of numerous risks which Defendants knew or should have known were associated with the Physiomesh, including but not limited to, the risks of the product's inhibition of tissue incorporation, pain, immunologic response, dehiscence, encapsulation, rejection, migration, scarification, shrinkage/contraction, degradation, deformation, adhesion to internal organs and viscera, erosion through adjacent tissue and viscera, intestinal obstruction, failure of repair/hernia recurrence, hernia incarceration or strangulation, or rupture/fracture of the mesh.

25. Defendants failed to adequately train or warn Plaintiff or her physicians about the necessity for invasive surgical intervention in the event of complications, or how to properly treat such complications when they occurred.

26. Defendants failed to adequately warn Plaintiff or her physicians that the necessary surgical removal of the Physiomesh in the event of complications would leave the hernia unrepaired, and would necessitate further medical treatment to attempt to repair the same hernia that the failed Physiomesh was intended to treat.

27. Defendants failed to adequately warn or train Plaintiff or her physicians that the surgery required to remove the Physiomesh in the event of complications would obviate any purported benefit associated with laparoscopic implantation, and would involve additional, significant risks to the patient.

28. Defendants represented to physicians, including Plaintiff's physicians, that the multi-layer coating would prevent or reduce adhesions and expressly intended for the Physiomesh to be

implanted in contact with the intestines and internal organs and marketed and promoted the product for said purpose.

29. Defendants failed to warn physicians that the multi-layer coating prevented tissue ingrowth, which is the desired biologic response to an implantable mesh device.

30. Defendants failed to warn physicians that the multi-layer coating was only temporary and therefore at best would provide only a temporary adhesion barrier, and when the coating inevitably degraded, the exposed polypropylene would become adhered to the organs or tissue.

31. With respect to the complications that were listed in the Defendants' warnings, Defendants provided no information or warning regarding the frequency, severity and duration of those complications, even though the complications associated with Physiomesh were more frequent, more severe and lasted longer than those with safer feasible alternative hernia repair treatments.

32. One of the purported benefits of the Physiomesh design was implantation using laparoscopy, which involves minimally invasive surgery. However, treatment of complications associated with Physiomesh often requires open surgery, thus obviating any purported benefit from the intended laparoscopic implantation technique.

33. In May 2016, Defendants issued an "Urgent: Field Safety Notice" relating to the Physiomesh product, the same product implanted in Plaintiff, and sent such notification to hospitals and medical providers in various countries worldwide. In this Urgent Field Safety Notice, Defendants advise these providers of "a voluntary product recall," citing two international device registries which reported data reflecting recurrence/reoperation rates being higher than that observed from a data set relating to patient outcomes after being implanted with other mesh.

Ethicon's "Urgent: Field Safety Notice" stated Ethicon believed the higher rates to be a multifactorial issue, including possible product characteristics. However, in the United States, Defendants failed to issue a nationwide recall, opting instead to simply remove the product from the market and cease further sales within the United States. Ethicon also knew or had reason to know that those implanted with the Ethicon Physiomesh Composite Mesh were still at risk for adverse events since Ethicon stated in the Field Safety Notice that those implanted with Physiomesh should continue to be followed. Despite its knowledge, Ethicon did not issue any warning, caution or instruction to hospitals, physicians or patients regarding the importance of monitoring for potential complications.

34. The manufacturing and design defects associated with the Physiomesh were directly and proximately related to the injuries suffered by the Plaintiff.

35. Neither Plaintiff nor her implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of Physiomesh. Moreover, neither Plaintiff nor their implanting physician were adequately warned or informed by Defendants of the risks associated with the Physiomesh or the frequency, severity, or duration of such risks.

36. On or about July 22, 2013, Plaintiff TRACEY HALLAC underwent a surgical procedure in which she was implanted with a Physiomesh Flexible Composite device.

37. Defendants developed, inspected, tested, assembled, designed, licensed, manufactured, distributed, packaged, supplied, marketed, advertised and/or sold, either directly or through third parties or related entities, the Physiomesh Flexible Composite device implanted into Plaintiff TRACEY HALLAC.

38. Plaintiff TRACEY HALLAC sustained injuries after being implanted with the Physiomesh Flexible Composite device.

39. The Physiomesh implanted in Plaintiff TRACEY HALLAC failed to reasonably perform as intended. The mesh failed, caused serious injury and required additional invasive surgery.

40. Plaintiff's severe adverse reaction, including the requirement for additional surgery, directly and proximately resulted from the defective and dangerous condition of the product and Defendants' defective and inadequate warnings about the risks associated with the product, and the frequency, severity and duration of such risks. Plaintiff has suffered, and will continue to suffer, both physical injury and pain, permanent and severe scarring and disfigurement, and has incurred substantial medical bills and other expenses, resulting from the defective and dangerous condition of the product and from Defendants' defective and inadequate warnings about the risks associated with the product.

41. As a result of her injuries resulting from the Physiomesh Flexible Composite device, Plaintiff TRACEY HALLAC has sustained pain and suffering, loss of enjoyment of life and other damages and will continue to suffer such losses into the future.

AS AND FOR A FIRST CAUSE OF ACTION, PLAINTIFF ALLEGES:

42. Plaintiff repeats and realleges paragraphs 1 through 41 as though fully set forth herein.

43. The Defendants had a duty to exercise reasonable care in the developing, testing, assembling, designing, licensing, labeling, manufacturing, distributing, packaging, supplying, ordering, marketing, detailing, advertising and selling of the Physiomesh Flexible Composite

device implanted into the Plaintiff including a duty to assure that the product did not pose a significantly increased risk of bodily harm and adverse events.

44. The Defendants failed to exercise ordinary care in the developing, inspecting, testing, assembling, designing, licensing, labeling, manufacturing, distributing, packaging, supplying, ordering, marketing, detailing, advertising and/or selling of the Physiomesh Flexible Composite device implanted into the Plaintiff.

45. The resulting injuries to the Plaintiff TRACEY HALLAC were caused solely by the negligence of the Defendants in failing to use reasonable care in developing, inspecting, testing, assembling, designing, licensing, labeling, manufacturing, distributing, packaging, ordering, marketing, detailing, advertising and/or selling the Physiomesh Flexible Composite device.

46. As a result of the foregoing, the Plaintiff TRACEY HALLAC has sustained severe, debilitating and permanent injuries and economic damages in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction.

AS AND FOR A SECOND CAUSE OF ACTION, PLAINTIFF ALLEGES:

47. Plaintiff repeats and realleges paragraphs 1 through 46 as though fully set forth herein.

48. The Defendants expressly warranted that the Physiomesh Flexible Composite device implanted into the Plaintiff was safe, effective and reasonably fit for use by the Plaintiff TRACEY HALLAC.

49. The product did not conform to these express representations because the product was defective and caused serious physical injury to consumers.

50. At all relevant times herein, the Plaintiff TRACEY HALLAC was using the product for the purpose and in the manner intended, and that by the use of reasonable care could not have both discovered these breaches and realized their danger.

51. As a result of Defendants' breach of express warranties, Plaintiff TRACEY HALLAC sustained severe, debilitating and permanent injuries and economic damages in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction.

AS AND FOR A THIRD CAUSE OF ACTION, PLAINTIFF ALLEGES:

52. Plaintiff repeats and realleges paragraphs 1 through 51 as though fully set forth herein.

53. At the time the Defendants developed, inspected, tested, assembled, designed, licensed, labeled, manufactured, distributed, packaged, supplied, ordered, marketed, detailed, advertised and/or sold the Physiomesh Flexible Composite device implanted into the Plaintiff, the Defendants knew the use for which it was intended and impliedly warranted the product to be of merchantable quality and safe and fit for its intended use.

54. Contrary to the Defendants' implied warranties, the Physiomesh Flexible Composite device was not of merchantable quality and was not safe for its intended use because the product was defective and unreasonably dangerous as described herein.

55. As a result of Defendants' breach of implied warranties, Plaintiff TRACEY HALLAC sustained severe, debilitating and permanent injuries and economic damages in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction.

AS AND FOR A FOURTH CAUSE OF ACTION, PLAINTIFF ALLEGES:

56. Plaintiff repeats and realleges paragraphs 1 through 55 as though fully set forth herein.

57. The Physiomesh Flexible Composite device implanted into the Plaintiff was designed, produced, manufactured, distributed, supplied and/or sold by the Defendants in a defective condition which included, but is not limited to, manufacturing defects, design defects and/or inadequate warnings or instructions.

58. The Defendants designed, produced, manufactured, distributed, supplied and/or sold the aforesaid product in a defective condition and are therefore liable to Plaintiff TRACEY HALLAC for the injuries she sustained in strict products liability.

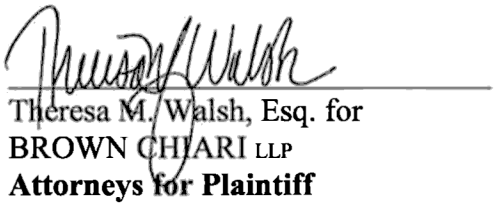
59. Plaintiff TRACEY HALLAC used the aforesaid product for its intended and foreseeable purpose.

60. As a result of the above, Plaintiff TRACEY HALLAC sustained severe, debilitating and permanent injuries and economic damages in an amount in excess of the jurisdictional limits of all lower courts which would otherwise have jurisdiction.

61. That one or more exceptions to the limited liability provisions of CPLR Article 16 apply herein.

WHEREFORE, Plaintiff TRACEY HALLAC, hereby demands judgment against the Defendants ETHICON, INC. and JOHNSON & JOHNSON, jointly and severally, for a sum that exceeds the jurisdictional limitations of all lower courts that would otherwise have jurisdiction in this action, together with the costs and disbursements of this action and punitive damages in an amount to be determined by a jury.

DATE: Buffalo, New York
March 17, 2023



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